IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	Confirmation No.: 5063
MACPHEE *et al.*	Art Unit: 1611
Appl. No.: 10/525,415	Examiner: Nathan, Shyam
§ 371 Date: January 10, 2006	Atty. Docket: 1327.0690001/ELE/KKD
For: **Hemostatic Dressing**	

Reply to Restriction Requirement

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

In reply to the Office Action dated **December 19, 2008**, requesting an election of one invention to prosecute in the above-referenced patent application, Applicants hereby provisionally elect to prosecute the invention of Group 1, represented by claims 1-15. This election is made without prejudice to or disclaimer of the other claims or inventions disclosed.

This election is made with traverse.

The Office contends that the claims in Groups 1-3 do not relate to a single inventive concept under PCT Rule 13.1 because they lack the same or corresponding technical features as required under PCT Rule 13.2. (Office Action, page 2). Specifically, the Office states that "the common technical feature among the invention is the hemostatic dressing which comprises a first fibrogen [sic] layer and thrombin layer adjacent to the first fibrinogen layer and a second fibrogen [sic] layer adjacent to said thrombidn [sic] layer which is found in Macphee et al. (WO/1999/059647) . . . . Thus the hemostatic dressing of Group I is not a contribution over the art . . . and it is not a

special technical feature as defined under PCT Rule 13.2, Part I (b). " (Office Action, pages 2-3). Applicants respectfully traverse these contentions.

Under PCT Rule 13.2, an alleged group of inventions claimed in a single application fulfill the unity of invention requirement of PCT Rule 13.1 when they share one or more of the same or corresponding special technical features. The phrase "special technical features," means "those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art." (PCT Rule 13.2). Applicants respectfully assert that the inventions of Groups 1-3 share a special technical feature that is a contribution over the prior art.

The present claims are directed to, *inter alia*, a hemostatic dressing comprising a first layer of fibrinogen, a thrombin layer adjacent to said first fibrinogen layer, and a second fibrinogen layer adjacent to said thrombin layer, *wherein the thrombin layer is noncoextensive with the first fibrinogen layer and/or the second fibrinogen layer.* In contrast, the Office has described Macphee *et al.* as allegedly teaching "a hemostatic bandage that can be used for treating wounded tissue in a patient which comprises: (i) a first fibrinogen layer; (ii) a thrombin layer adjacent to the first fibrinogen layer; and (iii) a second fibrinogen layer adjacent to the thrombin layer." (Office Action, page 2). Macphee *et al.* does not teach a hemostatic dressing comprising a thrombin layer that is noncoextensive with a first fibrinogen layer and/or a second fibrinogen layer, as required in the present claims. Accordingly, Applicants respectfully submit that a hemostatic dressing comprising a thrombin layer that is noncoextensive with a first fibrinogen layer

and/or a second fibrinogen layer is a special technical feature as defined under PCT Rule 13.2.

Additionally, the United States Patent and Trademark Office regulations provide guidance to Examiners in regard to unity of invention:

> (b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combination of categories: . . .
>
> > (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; . . . .

(37 C.F.R. § 1.475(b)(3)).

Similarly, the PCT International Search and Preliminary Examination Guidelines provides the following example of unity of invention:

> **Example 1**
>
> Claim 1: A method of manufacturing chemical substance X.
>
> Claim 2: Substance X.
>
> Claim 3: The use of substance X as an insecticide.
>
> Unity exists between claims 1, 2 and 3. The special technical feature common to all the claims is substance X.

(PCT International Search and Preliminary Examination Guidelines, Part III, Chapter 10).

In the present application, Groups 1-3 possess unity of invention because all of their respective claims reference the special technical feature of a hemostatic dressing

comprising a thrombin layer that is noncoextensive with a first fibrinogen layer and/or a second fibrinogen layer. Specifically, the claims in Group 1 are directed to a hemostatic dressing comprising a thrombin layer that is noncoextensive with a first fibrinogen layer and/or a second fibrinogen layer. The claims in Group 2 are directed to a method of treating wounded tissue comprising applying a hemostatic dressing comprising a thrombin layer that is noncoextensive with a first fibrinogen layer and/or a second fibrinogen layer. The claims in Group 3 are directed to a method of making a hemostatic dressing comprising a thrombin layer that is noncoextensive with a first fibrinogen layer and/or a second fibrinogen layer. Accordingly, Applicants respectfully submit that Groups 1-3 possess unity of invention and should be examined together.

Reconsideration and withdrawal of the Restriction Requirement, and consideration and allowance of all pending claims, are respectfully requested. Applicants retain the right to petition from the Restriction Requirement under 37 C.F.R. § 1.144.

Request for Rejoinder

The Examiner has required restriction between product (Group 1) and process of use claims (Group 2). The Examiner has also required restriction between product (Group 1) and process of manufacturing claims (Group 3). In accordance with the decisions in *In re Ochiai*, 71 F.3d 1565, 37 USPQ2d 1127 (Fed. Cir. 1995) and *In re Brouwer*, 77 F3d 1565, 37 USPQ2d 1663 (Fed. Cir. 1996), and the notice published in the Official Gazette on March 26, 1996, setting forth new guidelines for the treatment of restricted product and process claims (*see* 1184 O.G. 86), Applicants respectfully request

that if the restriction requirement is made final and if the claims of elected Group 1 are found allowable, then the claims of Groups 2 and 3 (claims 16-24) be rejoined and examined for patentability. *See also* M.P.E.P. § 821.04.

It is not believed that extensions of time are required, beyond those that may otherwise be provided for in accompanying documents. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefor are hereby authorized to be charged to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Kellie Weiss Registration No. 61,455

for Eldora L. Ellison
Attorney for Applicants
Registration No. 39,967

Date: _____

1100 New York Avenue, N.W.
Washington, D.C. 20005-3934
(202) 371-2600

926518_1.DOC